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The Blossom Project Online: Promoting physical activity during pregnancy in previously low-active women

Submission date 12/02/2014	**Recruitment status** No longer recruiting	[ ] Prospectively registered
		[ ] Protocol
Registration date 29/04/2014	**Overall study status** Completed	[ ] Statistical analysis plan
		[X] Results
Last Edited 17/12/2020	**Condition category** Pregnancy and Childbirth	[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to evaluate the effect of an online website to promote physical activity and prevent excess weight gain in previously low-active or sedentary pregnant women. We will also look at the impact of the mothers' physical activity and weight gain during pregnancy on their babies body measurements.

Who can participate?
Fifty healthy women between the ages of 18-45 years old, pregnant with one baby and less than 15 weeks gestation were recruited from central Iowa. Participants were low-active or sedentary, defined as less than three intentional bouts of 30 minutes of moderately intense physical activity per week for at least 6 months prior to conception.

What does the study involve?
Participants were randomly allocated to either a walking intervention or usual care between 10-14 weeks of pregnancy. Both groups of participants received access to the interactive website, but each group had access to different parts of the website. The usual care group had access to the part of the website that provided information about a healthy diet and physical activity recommendations specific to pregnancy. Women in the usual care group were not asked to make any specific changes to their physical activity and diet. The participants in the walking intervention group had access to the part of the website described above but also had access to the interactive part of the website. These participants were asked to gradually increase their physical activity to 30 minutes of walking on most if not all days of the week, to reach at least 150 minutes per week by week 19 of pregnancy, and continue until delivery. The mothers' weight gain during pregnancy was compared between the two groups, along with their adherence to the physical activity guidelines and their babies' body measurements at 1 month of age.

What are the possible benefits and risks of participating?
There was no immediate direct benefit from taking part in this study. If assigned to the walking intervention, participants were encouraged to participate in more physical activity during

pregnancy and meet current prenatal physical activity recommendations. The research findings will likely benefit society by increasing our understanding of the health benefits of physical activity during pregnancy and how to increase physical activity in previously low-active women. There were no foreseeable risks to either the participants or their babies by participating in this study. Participants may have experienced discomfort from fasting overnight prior to the blood draw at 24-26 weeks gestation and momentary pain during the blood draw. An experienced phlebotomist conducted all blood draws under strict sanitary conditions to minimize pain and risk of infection.

Where is the study run from?
The study was conducted by Iowa State University in collaboration with local obstetric clinics in and around central Iowa (USA).

When is the study starting and how long is it expected to run for?
Recruitment of participants occurred from January to September 2013. Data collection will continue until June 2014.

Who is funding the study?
Funding has been provided by the American Heart Association, Iowa State University College of Human Sciences, and the Sandy S. and Roy W. Uelner Professorship awarded to Dr Christina Campbell.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A randomized controlled trial to evaluate the efficacy of a behaviorally-based website to promote physical activity and prevent excessive gestational weight gain during pregnancy in previously low-active women

Study objectives
Excessive maternal weight gain during pregnancy affects nearly half of all pregnancies in the United States. A mother is then at risk for developing gestational diabetes and also is more likely to retain her excess weight after she's had the baby. Thus, she begins future pregnancies overweight or obese and again puts herself and her child at risk for several chronic diseases later in life, including type 2 diabetes mellitus and cardiovascular disease. Previous research has suggested that maternal physical activity may reduce the risk of gestational diabetes and excessive gestational weight gain. However, less than 25% of pregnant women meet current prenatal physical activity recommendations. This study will focus on increasing maternal physical activity during pregnancy in order to prevent excessive gestational weight gain.

Hypothesis: Mothers will successfully achieve appropriate pregnancy weight gain relative to pre-pregnancy body mass index (BMI) when given access to an interactive website to increase physical activity that includes goal setting tools and provides social support. Increased self-efficacy will increase adherence to prenatal physical activity recommendations compared to those women who do not have access to these tools. Furthermore, we hypothesize that the infants born to mothers who met current prenatal physical activity and weight gain recommendations will have more favorable body composition and birth outcomes compared to the babies born to mothers that did not meet these recommendations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Iowa State University Office for Responsible Research Humans Institutional Review Board (IRB), 11/12/2012, ID#: 11-286

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Excessive maternal weight gain during pregnancy

Interventions
Participants are recruited from obstetric clinics in central Iowa. Randomization is blinded to researchers and participants until after completion of baseline data collection. Participants are randomized to one of two groups:

1. The intervention group, who receive the walking intervention
2. The control group, who receive 'usual care'

An interactive website is used to facilitate the walking-based intervention. Both groups of research participants receive access to the website, but each group has access to different aspects of the website.

Usual care group
Participants randomized to this group have access to a portion of the website that provides information similar to that provided by their medical provider about a healthy diet and physical activity recommendations specific to pregnancy. Women in the usual care group are not asked to make any specific modifications to their current lifestyle (e.g., physical activity and dietary intake).

Intervention group
The participants in this group also have access to the informative aspect of the website as described above; however, they also utilize the interactive portion of the website. Additionally, these participants are asked to walk 30 minutes a day, 5 days a week for a total of 150 minutes of moderately intense walking per week. The interactive website provides individualized goal setting and problem solving modules, self-tracking of physical activity sessions (self-regulation), and social support for participants via interactive social networking with other participants. The website (www.blossomprojectonline.com) aims to increase physical activity among participants by improving self-efficacy, a key construct of the Social-Cognitive Theory. The website is password protected so that users are in control of their own privacy settings and also allows participant website usage to be tracked.

Walking-based intervention
Participants randomized to receive access to the interactive portion of the website begin the walking intervention no later than week 15 of pregnancy. The first four weeks are an acclimation period, designed to slowly increase walking time to reduce discomforts of starting a new physical activity program. By the end of week 18, each participant should be meeting current prenatal physical activity recommendations by walking at least 150 minutes per week or 30 minutes on most, if not all, days of the week. Women are expected to use the self-tracking features of the website to record daily physical activity (self-regulation). The walking intervention lasts until the birth of the baby.

Intervention Type
Behavioural

Primary outcome measure
1. Gestational weight gain was measured at baseline (10-14 weeks gestation), week 22-24 gestation, and week 34-36 gestation. Total gestational weight gain (to the nearest 0.1 kg) was defined as the last weight measured by the research staff between 34-36 weeks gestation minus self-reported pre-pregnancy weight. Pre-pregnancy weight was self-reported at enrollment. Excessive gestational weight gain was defined using the 2009 Institute of Medicine recommendations for total and weekly weight gain recommendations based on maternal pre-pregnancy BMI.
2. Infant body composition: measured at 4 weeks of age via air displacement plethysmography (Pea Pod; Life Measurement Inc., Concord, CA)

Secondary outcome measures
1. Maternal self-efficacy: assessed via validated surveys at baseline (10-14 weeks gestation), week 22-24 gestation, week 34-36 gestation, and 1-month postpartum
2. Maternal adherence to prenatal physical activity recommendations: assessed via objective physical activity monitoring (SenseWear®Mini armband) at baseline (10-14 weeks gestation), week 22-24 gestation, and week 34-36 gestation
3. Maternal insulin resistance: assessed via fasting blood glucose, insulin and a 1-hour 75 g oral glucose tolerance test between 24-26 weeks gestation
4. Infant birth outcomes: birth weight, length, head circumference, and APGAR scores (1 and 5 minutes post-delivery) obtained from the medical birth record

Overall study start date
01/01/2013

Completion date
01/06/2014

Eligibility

Key inclusion criteria
1. Healthy pregnant women between the ages of 18-45 years old living in the communities in and around Ames, Iowa with regular internet access
2. All women enrolled in the study are low active, defined as less than three intentional bouts of 30 minutes of moderately intense physical activity per week for at least 6 months prior to conception
3. If asked, women must be willing to walk 30 minutes on most days of the week throughout pregnancy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
50 women were recruited and enrolled in the study to allow for a 20% attrition rate and ensure 20 participants in each group will complete the study

Total final enrolment
45

Key exclusion criteria
1. Smoking during pregnancy
2. A non-singleton pregnancy
3. A history of chronic disease (e.g., type 1 diabetes, cardiovascular disease, untreated thyroid condition)
4. Any other disease or use of medication known to influence overall metabolism
5. Underweight prior to pregnancy (BMI < 18.5 kg/m2)
6. Inability to communicate due to language or mental status

Date of first enrolment
01/01/2013

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
United States of America

Study participating centre
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Organisation
Individual sponsor (USA)

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Sponsor type
Other

Funder(s)

Funder type
Research organisation

Funder Name
American Heart Association

Alternative Name(s)
American Heart Association, Inc., AMERICAN HEART ASSOC., American Heart Assn, Association for the Prevention and Relief of Heart Disease, AHA

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Funder Name
Iowa State University College of Human Sciences (USA)

Funder Name
Sandy S. and Roy W. Uelner Professorship (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2016	17/12/2020	Yes	No